Amendments to the Claims

WHAT IS CLAIMED IS:

1-17 (Withdrawn)

18. (Currently amended) A transgenic plant comprising a recombinant expression cassette stably integrated into the genome thereof, said cassette comprising a meristem-preferred promoter operably linked to a polynucleotide encoding isopentenyl transferase, ~~capable of effecting an increase in cytokinin activity,~~ wherein said transgenic plant displays enhanced vigor compared to a corresponding plant without said cassette ~~without significant detrimental effects of increased cytokinin activity~~.

19. (Currently amended) Seeds of the transgenic plant of Claim 18, wherein said seeds comprise the meristem-preferred promoter operably linked to a polynucleotide encoding isopentenyl transferase.

20. (Canceled)

21-22 (Withdrawn)

23-24. (Canceled)

25. (Currently amended) The transgenic plant of ~~Claim 23,~~ Claim 18, wherein said ~~recombinant expression cassette comprises the~~ promoter comprises a zag2.1 promoter ~~operably linked to a polynucleotide encoding a protein involved in cytokinin biosynthesis~~.

26-27. (Canceled)

28. (Currently amended) The transgenic plant of ~~Claim 23,~~ Claim 18, wherein said ~~recombinant expression cassette comprises the~~ promoter comprises a zap promoter ~~operably linked to a polynucleotide encoding a protein involved in cytokinin biosynthesis~~.

29. (Currently amended) The transgenic plant of ~~Claim 23,~~ Claim 18, wherein said ~~recombinant expression cassette comprises the~~ promoter comprises a tb1 promoter ~~operably linked to a polynucleotide encoding a protein involved in cytokinin biosynthesis~~.

30-32. (Canceled)

33. (Currently amended) The transgenic plant of ~~Claim 23~~ Claim 18, wherein said recombinant expression cassette further comprises ~~(1) a reproductive tissue-preferred promoter operably linked to a polynucleotide encoding a protein involved in cytokinin biosynthesis and (2)~~ one or more ~~promoters or~~ enhancer elements ~~of a highly expressed gene~~.

34. (Original) The transgenic plant of Claim 33 wherein the enhancer element comprises the 35S enhancer of cauliflower mosaic virus.

35. (Original) The transgenic plant of Claim 34 wherein the 35S enhancer comprises SEQ ID NO: 4.

36. (Currently amended) The transgenic plant of Claim 33 wherein the recombinant expression cassette comprises (1) ~~the~~ a zag2.1 promoter operably linked to a polynucleotide encoding *ipt* and (2) ~~the~~ a cauliflower mosaic virus 35S enhancer.

37. (Original) The transgenic plant of Claim 36 wherein the recombinant expression cassette comprises (1) SEQ ID NO: 3 operably linked to the coding region of SEQ ID NO: 1 and (2) SEQ ID NO: 4.

38-43 Withdrawn

44. (Currently amended) A method of modulating cytokinin activity in a plant, ~~wherein modulated cytokinin activity enhances plant vigor without significant detrimental effects,~~ comprising stably transforming said plant with a recombinant expression cassette comprising a meristematic promoter operably linked to a polynucleotide encoding isopentenyl transferase, wherein said transgenic plant

displays enhanced vigor compared to a corresponding plant without said cassette ~~to result in an increase in cytokinin activity~~.

45-48. (Canceled)

49. (Currently amended) The method of ~~Claim 45~~ Claim 44, wherein said ~~recombinant expression cassette comprises a~~ promoter is selected from the group consisting of zag2.1, zap, tb1, ~~eep1, eep2, F3.7, thxH, Zm40, ESR~~, PCNA2, ~~lec1, ZmCkx1-2, ZmCkx2, ZmCkx3, ZmCkx4, and ZmCkx5~~ and kn1.

50. (Currently amended) The method of ~~Claim 45~~ Claim 44, wherein said recombinant expression cassette further comprises ~~(1) a female reproductive-tissue-preferred promoter operably linked to a polynucleotide encoding a protein involved in cytokinin biosynthesis and (2)~~ one or more ~~promoters or~~ enhancer elements ~~of a highly expressed gene~~.

51. (Original) The method of Claim 50 wherein the enhancer element comprises the 35S enhancer of cauliflower mosaic virus.

52. (Original) The method of Claim 51 wherein the 35S enhancer comprises SEQ ID NO: 4.

53. (Currently amended) The method of Claim 50 wherein the recombinant expression cassette comprises (1) ~~the~~ a zag2.1 promoter operably linked to a polynucleotide encoding *ipt* and (2) ~~the~~ a cauliflower mosaic virus 35S enhancer.

54. (Original) The method of Claim 53 wherein the recombinant expression cassette comprises (1) SEQ ID NO: 3 operably linked to the coding region of SEQ ID NO: 1 and (2) SEQ ID NO: 4.

55-65 Withdrawn

66. (New) The transgenic plant of Claim 18, wherein said recombinant expression cassette comprises a PCNA2 promoter operably linked to a polynucleotide encoding a protein involved in cytokinin biosynthesis.

67. (New) The transgenic plant of Claim 18, wherein said recombinant expression cassette comprises a kn1 promoter operably linked to a polynucleotide encoding a protein involved in cytokinin biosynthesis.

68. (New) The transgenic plant of Claim 18, wherein the plant is maize, soybean, sunflower, safflower, canola, wheat, barley, rye, alfalfa, or sorghum.

69. (New) The transgenic plant of Claim 68, wherein the plant is maize or soybean.

Status of the Claims

Claims 18-20, 23-37, and 44-54, including SEQ ID NO: 1, 3, and 4, were examined in the Office Action dated August 9, 2006.

Claims 20, 23, 24, 26, 27, 30, 31, 32, 45, 46, 47, and 48 are canceled herewith.

Claims 18, 19, 25, 28, 29, 33, 36, 44, 49, 50, and 53 are amended herewith.

Original claims 34, 35, 37, 51, 52, and 54 remain pending.

New claims 66-69 are added.

Remarks

The Examiner has objected to several instances wherein Applicants failed to use sequence identifiers, or included a blank. The specification has been amended accordingly.

The claim for domestic priority in the first paragraph of the specification has been amended at the Examiner's request.

Applicants thank the Examiner for pointing out these items.

Claim Rejections under 35 USC 112, Indefiniteness

Claims 18-20, 23-36, and 44-53 have been rejected as indefinite.

Claims 18 and 44 were rejected for the recitation "significant." Claims 18 and 44 have been amended, obviating the rejection.

Claims 33 and 50 were rejected for the recitation "highly expressed gene." The claims have been amended and the rejection is obviated.

Claim 31 was rejected for the recitation "low-level." Claim 31 has been canceled.

Claims 25-30, 32, 36, 49, and 53 were rejected for recitation of promoter names as being arbitrary and creating ambiguity.

Applicants traverse this rejection.

"The amount of detail required to be included in claims depends on the particular
invention and the prior art, and is not to be viewed in the abstract but in conjunction with whether the specification is in compliance with the first

paragraph of section 112." *Shatterproof Glass Corp. v. Libbey-Owens Ford Co.*, 758 F.2d 613, 225 USPQ 634 (Fed. Cir. 1985).

Applicants respectfully submit that the promoter names are not arbitrary or ambiguous when the claims are read in light of the specification. For each promoter originally named in the claims, the specification provides (1) an exemplary promoter corresponding to the named promoter, as shown in the sequence listing; and (2) patent and/or non-patent literature references further describing each promoter and its expression. See, for example, pages 16 and 43-44. The kn1 promoter, newly named in the claims, is supported by the reference on page 44, lines 16-19. "A claim is not 'indefinite' simply because it is hard to understand when viewed without benefit of the specification." *S3 Inc. v. nVIDIA Corp.*, 259 F.3d 1364, 59 USPQ2d 1745 (Fed. Cir. 2001). Further, the Court has held that claims need only "reasonably apprise those skilled in the art" as to their scope and be "as precise as the subject matter permits." *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 USPQ 81 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987). Applicants respectfully submit that the language of the claims is sufficiently definite when read in conjunction with the specification.

In view of the amendments and remarks made herein, Applicants request that all rejections for indefiniteness be withdrawn.

Claim Rejections under 35 USC 112, Written Description

Claims 18-20, 23-36, and 44-53 have been rejected as failing to meet the written description requirement. The Examiner states that the written description rejection is directed in part towards: (1) any expression cassette effecting any increase in cytokinin activity; (2) any expression cassette comprising any polynucleotide encoding any protein involved in cytokinin biosynthesis; (3) any polynucleotide encoding any IPT protein; (4) any promoter driving low-level constitutive expression; (5) any expression cassette comprising a reproductive-tissue preferred promoter and one or more enhancer elements of a highly expressed gene.

As to parts 1, 2, 4, and 5, the claims have been amended and the rejection is obviated.

As to part 3, Applicants traverse. Applicants respectfully submit that adequate support is provided for methods and compositions comprising a broad range of polynucleotides encoding isopentenyl transferase. The Applicants direct the Examiner's attention to the specification at page 4, lines 3 through 22, which refers to *ipt* genes from Arabidopsis and maize as well as Agrobacterium. Further, Applicants respectfully submit that *Lilly* provides a standard for "an adequate written description of a DNA" to be claimed. (emphasis added) Where, as here, the claims are not directed to the *ipt*-encoding DNA *per se*, but to methods and combinations of which such DNA is a functional component, functionality becomes the determinative quality and the basis for adequate written description.

The claimed invention provides novel constructs comprising a polynucleotide encoding an isopentenyl transferase operably linked to a meristematic promoter, and novel methods of use of said constructs to create improved plants. The sequence listing, at SEQ ID NO: 1, provides the sequence of an *ipt* gene isolated from *Agrobacterium tumefaciens* (Strabala et al. (1989) *Mol. Gen. Genet.* 216:388-394). The specification states, with reference to polynucleotides encoding cytokinin biosynthetic enzymes, that polynucleotides other than those provided in the sequence listing may be used in the invention; see, for example, page 4, lines 3 through 22.

There is no requirement for Applicant to discover or disclose every possible species within the claimed genus. It is well within the knowledge of a person of skill in the art to substitute homologous or analogous genes to achieve the desired result. The invention encompasses use of polynucleotides encoding polypeptides which retain substantially the same, or increased, biological function or activity (see, e.g., p. 35, lines 22-26), including a synthetic polypeptide. Clearly, the *function* of the encoded polypeptide is the common element, and the biological or chemical *source* is not critical.

A person of skill in the art, provided with the disclosure of this application, would recognize that alternative isopentenyl transferase genes could be used. At the time of filing this application, *ipt* genes had been identified not only in *Agrobacterium* but also in at least two plant species, Arabidopsis (Takei et al. (2001) J. Biol. Chem. 276:26405-26410; Sun et al. (2003) Plant Physiol. 131:167-176) and petunia (Zubko et al. (2002) Plant J. 29(6):797-808). Additional plant *ipt* genes were in the process of

being isolated and were subsequently published. See, for example, U.S. patent publication 2006-0064786 (maize); Sakano et al. (2004) Phytochem. 65:2439-2446 (hop); and GenBank accession XM_477138 (rice, 2004).

Applicants also respectfully submit that the written description analysis of *Lilly* was further refined in *Amgen Inc. v. Hoechst Marion Roussel*, 314 F.3d 1313, 65 USPQ2d 1385 (Fed. Cir. 2003). In *Amgen*, the court ruled that *Lilly* did not hold that all functional descriptions of genetic material necessarily fail to meet the written description requirement. The Federal Circuit supported the district court's finding that:

> "When the claim is to a composition rather than a process, the written description requirement does not demand that the specification describe technological developments in the way in which the claimed composition is made that may arise after the application is filed." (citations omitted)

Thus, it is the claimed invention which must be adequately described, not every means possible of attaining the invention, and certainly not those means which "may arise after the application is filed." In the present case, the written description requirement should not demand that the specification describe all genes encoding all proteins *of a particular function*, including those which may arise (i.e. be isolated) after the application is filed. The specification provides support for a defined construct (i.e. a polynucleotide encoding isopentenyl transferase, linked to a meristematic promoter) providing a targeted function (i.e., isopentenyl transferase activity) for a specific purpose (i.e., improved vigor). Claims are directed to the effect on vigor which results from targeted expression of a functional isopentenyl transferase gene. The *ipt* gene per se is not claimed, and its specific source need not be described. Where persons of skill in the art would understand and recognize that the inventor invented *what is claimed*, the written description requirement is met.

In view of the amendments and remarks made herein, Applicants request that all rejections for written description be withdrawn.

Claim Rejections under 35 USC 112, Enablement

Claims 18-20, 23-36 and 44-53 have been rejected for failing to meet the enablement requirement.

Amendments to the claims have obviated numerous rejections set forth by the Examiner on page 7 of the Office Action. Applicants respectfully assert that the current claims are adequately supported by the specification. The use of meristem-preferred promoters is described, for example, on page 12, lines 16-24, and on page 30, lines 3-7. Meristem-preferred promoters are included in the listing of promoters on pages 43 and 44. Experimental results, including Examples 9 and 10 (pp. 108-109), document improved vigor as reflected in plant height and leaf greenness.

The Examiner states that "due to the unpredictable nature of plant transformation with proteins that alter hormone activities, one of skill in the art cannot reasonably generate transformed plants with a desired phenotype using a specific isolated gene." (Office Action, p. 9) The Examiner cites Estruch et al. (1993, The Plant Journal 4(2):379-384), who reported developmental abnormalities observed in somatic mosaics created by transposon-activated expression of *ipt* in transgenic tobacco. The Examiner quotes the specific statement "The occurrence of such abnormalities correlates with an increase in cytokinin within the floral tissue" (Estruch, p. 379). However, the "floral tissue" described by Estruch is epiphyllous, i.e. resulting from ectopic meristems on leaf tissue, as the *ipt* gene of Estruch et al. is linked to a constitutive promoter. In the present application, the meristem-preferred expression claimed is clearly distinct from constitutive expression, and the inventors' selection of the appropriate promoters needed to achieve the desired result is a part of their inventive contribution.

The Examiner cites the findings of Roeckel et al. (1997, Transgenic Research 6(2):133-141), where seed-specific expression of the *ipt* gene of *Agrobacterium* resulted in effects on root length and number of branches in tobacco or canola. Applicants respectfully submit that activity of the AT2S1 promoter is confined to the embryo axis and as such would not be considered a meristematic promoter. Native expression of At2S1 is described at Figure 6 and page 1050 in Bies-Etheve et al. (1999) Plant Molecular Biology 40:1045-1054, a copy of which is attached as Appendix A.

The Examiner cites the findings of Sa et al. (2002, Transgenic Research 11(3):269-278) at "page 12, 5th paragraph". Applicants respectfully ask that the Examiner clarify the citation, as there are only 10 pages in the reference.

The Examiner cites the findings of Takei et al. (2001, Journal of Biological Chemistry 276(28):26405-26410) as teaching that multiple routes have been proposed in cytokinin biosynthesis and that tRNA degradation is "not a major source of cytokinin." Applicants submit that this paper reflects the knowledge of one of skill in the art at that time, and that the phylogenetic tree of Figure 1B and the discussion of sequence motifs on page 26409 establish that undue experimentation would not be required for one of skill in the art to determine whether a putative *ipt* gene would be useful in the invention as claimed.

In view of the amendments and remarks made herein, Applicants ask that all rejections as to enablement be withdrawn.

Claim Rejections under 35 USC 102, Anticipation

Claims 18-20, 23-24, and 44-48 have been rejected under 35 USC 102(b) as anticipated by Amasino et al. (5,689,042), which discloses a senescence-associated promoter driving isopentenyl transferase.

Claim amendments have obviated the rejection, as a senescence-associated promoter is not a meristematic promoter.

Claims 18-20, 23-24, 31, 33, 44-48, and 50 have been rejected under 35 USC 102(e) as anticipated by Martineau (6,329,570). The Examiner states that "Martineau discloses a transgenic plant and method for increasing the rate of boll production and number of bolls" produced by a cotton plant transgenic for an *ipt* gene operably linked to promoter functional in a cotton ovule integument cell.

Claim amendments have obviated the rejection, as a promoter functional in a cotton ovule integument cell is not a meristematic promoter.

In view of the amendments and remarks made herein, Applicants ask that all rejections as to anticipation be withdrawn.

Rejection – Double Patenting

Claims 18-20, 23-37 and 44-54 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,992,237 B1.

Applicants respectfully submit that claim amendments have obviated the double-patenting rejection. However, should the rejection be sustained, a terminal disclaimer to the commonly-owned patent will be executed upon allowance of claims in the present application.

Rejection under 35 USC 101

Claim 19 has been rejected as directed to non-statutory subject matter.

Claim 19 has been amended as suggested and the rejection is obviated.

In view of the above amendments and remarks, Applicants respectfully submit that all grounds for rejection have been overcome and that the claims as amended are in condition for allowance.

The Commissioner is hereby authorized to charge the payment of any fees under 37 C.F.R. §1.20(a) concerning this transaction, if they should be deemed applicant's mistake, or to credit any overpayment, to Deposit Account No. 16-1852.

Respectfully submitted,

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